UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

LEAH ODOM,

Plaintiff,

vs.

PFIZER INC.; VIATRIS INC.; GREENSTONE LLC; PRASCO, LLC d/b/a PRASCO LABS.; PHARMACIA & UPJOHN CO. LLC; **and PHARMACIA LLC**,

Defendants.

PERSONAL INJURY/
PRODUCTS LIABILITY ACTION

COMPLAINT
JURY TRIAL DEMANDED

This case relates to:
3:25-md-3140-MCR HTC

Plaintiff, Leah Odom, by and through Plaintiff's undersigned counsel, brings this civil action against Defendants for personal injuries and damages suffered by Plaintiff, and alleges upon information and belief as follows:

INTRODUCTION

1. This is an action for damages related to Defendants' wrongful conduct in connection with the development, design, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of medroxyprogesterone acetate (hereinafter "MPA"), also known as depot medroxyprogesterone acetate (hereinafter "DMPA"). Defendants' trade name for this prescription drug is Depo-Provera® **(**hereinafter "Depo-Provera").

2. Defendants manufacture, promote, and sell Depo-Provera as a prescription drug used for contraception and/or to treat endometriosis, among other indications. Depo-Provera is manufactured as an injection to be administered intramuscularly every three (3) months in either the upper arm or buttocks.

3. Depo-Provera injured Plaintiff Leah Odom by causing or substantially contributing to the development of an intracranial meningiomas, *i.e.*, brain tumor, which required significant and invasive treatment and has resulted in serious injuries.

4. Defendants knew or should have known for decades that Depo-Provera, when administered and prescribed as intended, can cause or substantially contribute to the development of meningiomas.

5. Several scientific studies have established that progesterone, its synthetic analogue progestin, and Depo-Provera in particular, cause or substantially contribute to the development of intracranial meningioma, a type of brain tumor.

6. Nevertheless, Defendants failed to warn, instruct, advise, educate, or otherwise inform Depo-Provera users and prescribers about the risk of intracranial meningioma or the need for monitoring for resultant symptoms.

7. To date, the U.S. label for Depo-Provera still makes no mention of the increased risk to patients of developing intracranial meningiomas despite the fact that the European Union ("EU") and the United Kingdom labels now list meningioma under the "special warnings and precautions for use" section and advise EU patients to speak with their doctors before using Depo-Provera if they have any history of meningioma.

8. Moreover, the Canadian label for Depo-Provera has listed "meningioma" among its "Post-Market Adverse Drug Reactions" since at least 2015.

9. As a proximate result of Defendants' wrongful actions and inactions, Plaintiff was injured and suffered damages from Plaintiff's use of Depo-Provera including but not limited to:

(i) Serious personal injuries

(ii) Physical pain and suffering

(iii) Mental and emotional distress

(iv) Invasive treatment and scarring

(v) Medical expenses—past, present, and future

(vi) Loss of enjoyment of life—past, present, and future

(vii) Lost income from her job

(viii) Injuries and damages on such other and further particulars as the evidence may show

10. Plaintiff therefore demands judgment against Defendants and requests, among other things, compensatory damages, statutory damages, attorneys' fees, and costs.

PARTIES

11. At all relevant times hereto, Plaintiff Leah Odom (hereinafter "Plaintiff") was and is a resident and citizen of Dorchester County, South Carolina.

12. Defendant PFIZER INC. (hereinafter "Pfizer") is a corporation organized under Delaware law with its principal place of business at The Spiral, 66 Hudson Boulevard East, New York, New York 10001.

13. Pfizer has a registered agent for service of process, C T Corporation System, 2 Office Park Court, Suite 103, Columbia, SC 29223.

14. Defendant VIATRIS INC. (hereinafter "Viatris") is a corporation organized under Delaware law with its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

15. Defendant GREENSTONE LLC (hereinafter "Greenstone") is a limited liability corporation organized under Delaware law with its principal place of business at Pfizer Peapack Campus, 100 Route 206 North, Peapack, New Jersey 07977.

16. Defendant PRASCO, LLC d/b/a PRASCO LABS. (hereinafter "Prasco") is a corporation organized under Ohio law with its principal place of business at 6125 Commerce Court, Mason, Ohio 45040.

17. Defendant PHARMACIA & UPJOHN CO. LLC (hereinafter "Pharmacia & Upjohn" or "Upjohn") is or was a corporation organized under Michigan law and headquartered at 7000 Portage Road, Kalamazoo, MI 49001.

18. Pharmacia & Upjohn has a registered agent for service of process, C T Corporation System, 2 Office Park Court, Suite 103, Columbia, SC 29223.

19. Defendant PHARMACIA LLC (hereinafter "Pharmacia") is a corporation organized under Delaware law and headquartered at Pfizer Peapack Campus, 100 Route 206 North, Peapack, New Jersey 07977.

20. Defendant Pfizer is the current New Drug Application (hereinafter "NDA") holder for Depo-Provera and has solely held the NDA for Depo-Provera since 2020. Upon information and belief, Pfizer has effectively held the NDA since at least 2002 when it acquired Pharmacia & Upjohn—who then held the NDA—as a wholly owned subsidiary. No later than 2003 did Pfizer's name appear on the label alongside Pharmacia & Upjohn.

21. At all relevant times, Defendant Pharmacia & Upjohn was a wholly owned subsidiary of Defendant Pfizer until Upjohn was spun off in a merger in 2020 to create Defendant Viatris and the remnant, i.e., Defendant Pharmacia, was retained by Pfizer.

22. Defendant Greenstone, founded in 1993, was a wholly owned subsidiary of Pfizer, that at pertinent times was in the business of offering a product portfolio of "authorized generic" medicines, including Depo-Provera.

23. Defendant Greenstone is a company that until November 2020 was styled as a wholly owned subsidiary of Pfizer but was in fact exclusively staffed with Pfizer personnel who reported to Pfizer's HR department, were on Pfizer's payroll, and shared the same corporate space with Pfizer in Peapack, New Jersey. Pfizer also managed Greenstone's key business functions including financial and sales analysis, business technology, customer service, legal matters, intellectual property, and supply chain operations. Thus, Greenstone was effectively a department within Pfizer.

24. Defendants Greenstone/Pfizer sold a "generic" version of Depo-Provera that was in fact what is known as an "authorized generic." Unlike standard generics, which must contain only the same active ingredients and have the same pharmaceutic effect but can otherwise contain vastly different additives, "authorized generics" are exact replicas of the brand name drug, with the identical chemical composition, simply marketed without the brand-name on its label. In other words, Greenstone was presenting itself as a distinct generic manufacturing entity when it was in fact Pfizer personnel producing the exact same brand-name Depo-Provera at Pfizer's own facility.

25. The FDA has stated that the term "authorized generic" drug is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. An "authorized generic" may be marketed by the brand name drug company, or another company with the brand company's permission.[1]

[1] *See* https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs (last accessed December 30, 2024).

26. Indeed, Pfizer's own website still states that "GREENSTONE Authorized Generics are manufactured to the same standards and at the same facilities as Pfizer brand-name drugs."[2]

27. Pfizer was the actual manufacturer of the authorized generic product that Greenstone distributed and sold.

28. Defendant Viatris was formed by the merger of Upjohn, Greenstone, and another company, Mylan N.V., in November 2020. Viatris is thus merely the latest iteration of Upjohn and Greenstone.

29. Even after the merger, Defendant Greenstone has continued to operate from the same location at Pfizer's corporate offices in Peapack, New Jersey.

30. Additionally, Defendant Pfizer retained 57% ownership of Viatris stock, making Pfizer the majority owner of Viatris, and since Pfizer retained the remnants of Pharmacia, Pfizer effectively remains the majority owner of Defendants Pharmacia & Upjohn and Greenstone.

31. Defendant Prasco is another "authorized generic" manufacturer of Depo-Provera, meaning Prasco simply takes brand-name Depo-Provera manufactured by Defendants Greenstone and/or Pfizer and distributes it as its own generic product.

32. Defendant Prasco consistently maintains a sizeable percentage of the market share for Depo-Provera sales in the United States.

33. Pfizer is the actual manufacturer of the authorized generic product that Prasco distributes and sells. Pfizer packages and labels the product with the Prasco name on the label under the Pfizer NDA.

[2] *See* https://www.pfizer.com/news/press-release/press-release-detail/pfizers-greenstone-and-digital-mens-health-clinic-roman (last accessed December 30, 2024).

34. All Defendants do business in South Carolina by, among other things, distributing, marketing, selling, and/or profiting from brand name and/or "authorized generic" Depo-Provera in South Carolina, as well as throughout the United States.

35. At all times material herein, Defendants were, and still are, pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Depo-Provera and its "authorized generic" version, in South Carolina, and throughout the United States.

JURISDICTION AND VENUE

36. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332, as the amount in controversy exceeds $75,000.00, and the Parties are citizens of different States.

37. All Defendants regularly conduct business in South Carolina.

38. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

39. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim, including the distribution, sale, and administration of Depo-Provera to Plaintiff and Plaintiff's development and treatment of meningiomas, all occurred in South Carolina.

CONDITIONS PRECEDENT

40. All conditions precedent to the filing of this action and to the Plaintiffs' right to the relief sought have occurred, have been performed, or have been excused.

PLAINTIFF LEAH ODOM'S SPECIFIC FACTS

41. In or around 2003, at or around the age of 33, Plaintiff Leah Odom was first administered Depo-Provera for contraception at Low Country Women's Specialists in

Summerville, SC and Newton Family Medicine in Charleston, SC.

42. Thereinafter, from approximately 2003 to 2006, and from 2008 to 2010, Plaintiff received brand-name and generic Depo-Provera injections every three (3) months for contraception at Low Country Women's Specialists and Newton Family Medicine, pursuant to her physicians' prescriptions.

43. At all times relevant herein, Defendants represented Depo-Provera to be appropriate, safe, and suitable for such purposes through the label, packaging, patient inserts, and advertising.

44. Over time, Plaintiff developed frightening symptoms. Prior to her diagnosis in July of 2019, Plaintiff developed forgetfulness, cognitive impairment ("brain fog"), depression, vision problems, difficulty with coordination and motor control, and unexplained weight gain despite diet and exercise. These problems caused her to work primarily from her bed for nearly all of 2019.

45. In July 2019, Dr. John Kerrison, Plaintiff's Retina Specialist, diagnosed Plaintiff with a meningioma after an MRI.

46. In September 2019, Plaintiff underwent brain surgery at the Medical University of South Carolina in Charleston, South Carolina to remove the meningioma. Dr. William Vandergrift performed Plaintiff's surgery.

47. Following surgery, Plaintiff was out of work for approximately three months.

48. As a result of Defendants' actions and inactions, Plaintiff has suffered serious injuries and damages due to Plaintiff's development of an intracranial meningioma, surgery, and sequelae related thereto.

49. Plaintiff was unaware until very recently, following publicity associated with a large case control study in France published in March 2024, that Depo-Provera had any connection

to her meningioma.

GENERAL ALLEGATIONS

A. Intracranial Meningioma

50. Intracranial meningioma is a medical condition in which a tumor forms in the meninges, the membranous layers surrounding the brain and spinal cord.

51. Although the tumor formed by an intracranial meningioma is typically histologically benign (meaning it usually does not metastasize), the growing tumor can nevertheless press against the sensitive surrounding tissues, i.e., the brain, and thereby cause a number of severe and debilitating symptoms ranging from seizures and vision problems to weakness, difficulty speaking, and even death, among others. Moreover, a sizeable number of meningiomas (15-20%) do become metastatic, greatly increasing their danger.

52. Treatment of a symptomatic intracranial meningioma typically requires highly invasive brain surgery that involves the removal of a portion of the skull, i.e., a craniotomy, in order to access the brain and meninges. Radiation therapy and chemotherapy may also be required as the sensitive location of the tumor in the brain can render complete removal highly risky and technically difficult.

53. Due to the sensitive location of an intracranial meningioma immediately proximate to critical neurovascular structures and the cortical area, surgery can have severe neurological consequences. Many studies have described the potential for postoperative anxiety and depression and an attendant high intake of sedatives and antidepressants in the postoperative period. Surgery for intracranial meningioma can also lead to seizures requiring medication to treat epilepsy. Moreover, meningiomas related to progesterone-based contraceptives tend to manifest at the base of the skull where removal is even more challenging, further increasing the risks of

injuries.

B. Depo-Provera

54. Depo-Provera (depot medroxyprogesterone acetate, hereinafter "DMPA") was first approved by the FDA in 1992 to be used as a contraceptive, and later, with the approval of the Depo-SubQ Provera 104 variant in 2004, as a treatment for endometriosis.

55. Depo-Provera is administered as a contraceptive injection that contains a high dose of progestin, a synthetic progesterone-like hormone that suppresses ovulation.

56. According to a recent National Health Statistics Report published in December 2023, nearly a quarter (24.5%) of all sexually experienced women ages 15-49 in the United States between 2015 and 2019 had ever used Depo-Provera.[3]

57. According to that same report, those proportions increase even further for Hispanic (27.2%) women and Black (41.2%) women who had ever used Depo-Provera.[4]

58. Depo-Provera is a 150 mg/mL dosage of DMPA that is injected every three (3) months into the deep tissue musculature of either the buttocks or the upper arm, with present labelling recommending alternating the injection site at each injection.

59. Defendant Pfizer represents Depo-Provera to be one of the most effective contraceptives in existence. In fact, the Depo-Provera label groups injectable contraceptives like Depo-Provera alongside "Sterilization" as the most effective contraceptive methods resulting in the fewest unintended pregnancies.

60. Among reproductive age women who used any form of contraception from 2017-2019, the contraceptive injection was most often used by young women, lower-income women,

[3] Daniels, K et al., "Contraceptive Methods Women Have Ever Used: United States, 2015-2019", *Nat'l Health Statistics Report*, No. 195, Dec. 14, 2023.
[4] *Id.*

and Black women.[5]

61. Depo-Provera was first developed by Defendant Upjohn (later acquired by Defendant Pfizer) in the 1950s.

62. Upjohn introduced Depo-Provera as an injectable intramuscular formulation for the treatment of endometrial and renal cancer in 1960.

63. The NDA for Depo-Provera for use as a contraceptive was originally submitted to the FDA by Upjohn in 1967; however, this application was rejected.

64. Upjohn again applied to the FDA for approval to market Depo-Provera as a contraceptive in 1978 but was again rebuffed.

65. Upjohn applied to the FDA for a third time for the approval of Depo-Provera as a contraceptive in 1983, but the FDA once again rejected the application.

66. As early as 1969, Upjohn successfully received approval for Depo-Provera for contraception in international markets, including France.

67. Upjohn's NDA for Depo-Provera for use as a contraceptive was eventually approved by the FDA on or about October 29, 1992.

68. Upjohn merged with Swedish manufacturer Pharmacia AB to form Pharmacia & Upjohn in 1995.

69. Defendant Pfizer acquired Pharmacia & Upjohn in 2002, thereby acquiring the Depo-Provera NDA as well as the associated responsibilities and liabilities stemming from the manufacturing, sale, and marketing of Depo-Provera.

70. Pfizer has effectively held the Depo-Provera NDA since acquiring Pharmacia &

[5] *See* https://www.kff.org/womens-health-policy/fact-sheet/dmpa-contraceptive-injection-use-and-coverage/ (last accessed December 30, 2024).

Upjohn in 2002, and has solely held the NDA since 2020.

71. Throughout the time Defendants marketed Depo-Provera, Defendants failed to provide adequate warnings to patients and the medical community, including Plaintiff's prescribing physician, of the risks associated with using the drug.

72. Defendants also failed to adequately test Depo-Provera to investigate the potential for intracranial meningioma.

73. Defendants are also liable for the conduct of its predecessors who failed to adequately design, test, and warn of the dangers associated with use of Depo-Provera.

C. The Dangers of Depo-Provera

74. The association between progesterone and meningioma has been known or knowable for decades, particularly for sophisticated pharmaceutical corporations like Defendants engaging in FDA-required post-market surveillance of their products for potential safety issues. That duty includes an obligation to keep current with emerging relevant literature and where appropriate, perform their own long- term studies and follow-up research.

75. Since at least 1983, the medical and scientific communities have been aware of the high number of progesterone receptors on meningioma cells, especially relative to estrogen receptors.[6]

76. This finding was surprising and notable within the medical and scientific communities because it had previously been thought that meningioma cells, like breast cancer cells, would show a preference for estrogen receptors.[7] Researchers publishing in the *European*

[6] *See* Blankenstein, et al., "Presence of progesterone receptors and absence of oestrogen receptors in human intracranial meningioma cytosols," *Eur J Cancer & Clin Oncol*, Vol. 19, No. 3, pp. 365-70 (1983).
[7] *See id.*

Journal of Cancer and Clinical Oncology instead found the opposite, indicating progesterone was involved in the incidence, mediation, and growth rate of meningiomas.[8] This particular study was published nearly a decade before the FDA approved Depo-Provera for contraception in 1992. In those nine (9) years before Depo-Provera was approved for contraception, and in the thirty-two (32) years since—more than forty (40) years in all—Defendants have seemingly failed to investigate the effect of their high-dose progesterone Depo-Provera on the development of meningioma.

77. Since at least as early as 1989, researchers have also been aware of the relationship between progesterone-inhibiting agents and the growth rate of meningioma.[9] That year, the same authors published a study in the *Journal of Steroid Biochemistry* entitled, "Effect of steroids and anti-steroids on human meningioma cells in primary culture," finding that meningioma cell growth was significantly reduced by exposure to mifepristone, an antiprogesterone agent.[10]

78. Numerous studies published in the decades since have presented similar findings on the negative correlation between progesterone-inhibiting agents and meningioma.[11]

79. Relatedly, a number of studies published in the interim have reported on the positive correlation between a progesterone and/or progestin medication and the incidence and growth rate of meningioma.[12]

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[8] *See id.*
[9] *See* Blankenstein, et al., "Effect of steroids and antisteroids on human meningioma cells in primary culture," *J Steroid Biochem*, Vol. 34, No. 1-6, pp. 419-21 (1989).
[10] *See id.*
[11] *See, e.g.*, Grunberg, et al., "Treatment of unresectable meningiomas with the antiprogesterone agent mifepristone," *J Neurosurgery*, Vol. 74, No. 6, pp. 861-66 (1991); *see also* Matsuda, et al., "Antitumor effects of antiprogesterones on human meningioma cells in vitro and in vivo," *J Neurosurgery*, Vol. 80, No. 3, pp. 527-34 (1994).
[12] *See, e.g.*, Gil, et al., "Risk of meningioma among users of high doses of cyproterone acetate as compared with the general population: evidence from a population-based cohort study," *Br J Clin Pharmacol*. Vol. 72, No. 6, pp. 965-68 (2011); *see also* Bernat, et al., "Growth stabilization and

80. In 2015, a retrospective literature review published in the peer-reviewed journal *BioMed Research International* by Cossu, et al. surveyed the relevant literature including many of the studies cited above and concluded that mifepristone, an antiprogesterone agent, had a regressive effect on meningioma, meaning it stopped or reversed its growth.[13] Reviewing the Blankenstein studies as well as many others conducted over a span of more than thirty (30) years, the authors concluded that mifepristone competes with progesterone for its receptors on meningioma cells and, by blocking progesterone from binding, stems or even reverses the growth of meningioma.

81. In light of the aforementioned studies, for several decades the manufacturers and sellers of Depo-Provera, Defendants, had an unassignable duty to investigate the foreseeable potential that a high dose synthetic progesterone delivered in the deep tissue could cause the development or substantially contribute to the growth of meningioma. Defendants were also best positioned to perform such investigations. Had Defendants done so, they would have discovered decades ago that their high dose progestin Depo-Provera was associated with a highly increased risk of meningioma and would have spared Plaintiff and countless others the pain and suffering associated with meningioma. Instead, Defendants did nothing, and therefore willfully failed to apprise the medical community, and the women patients receiving quarterly high dose injections, of this dangerous risk.

82. Indeed, more recently, researchers have found that prolonged use (greater than one

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regression of meningiomas after discontinuation of cyproterone acetate: a case series of 12 patients," *Acta Neurochir* (*Wien*). Vol. 157, No. 10, pp. 1741-46 (2015); *see also* Kalamarides, et al., "Dramatic shrinkage with reduced vascularization of large meningiomas after cessation of progestin treatment," *World Neurosurg.* Vol. 101, pp 814.e7-e10 (2017).

[13] *See* Cossu et al., "The Role of Mifepristone in Meningiomas Management: A Systematic Review of the Literature" *BioMed Res. Int.* 267831 (2015), https://doi.org/10.1155/2015/267831

year) of progesterone and progestin, and specifically Depo-Provera, is linked to a greater incidence of developing intracranial meningioma, as would be expected based on all the aforementioned studies and recognition of the relationship between dose and duration of use and the development of adverse events well recognized in the fields of pharmacology, toxicology, and medicine.

83. In 2022, an article was published in the journal *Endocrinology* entitled "Estrogen and Progesterone Therapy and Meningiomas."[14] This retrospective literature review noted that a "dose-dependent relationship" has been established between at least one progestin and the incidence and growth rate of meningioma. The study authors further noted that progesterone-mediated meningiomas appear to be located most often in the anterior and middle base of the skull and are more likely to be multiple and require more intensive treatment.

84. In 2023, researchers reported on a direct link between Depo-Provera and meningioma. That year a case series was published in the *Journal of Neurological Surgery Part B: Skull Base* titled "Skull Base Meningiomas as Part of a Novel Meningioma Syndrome Associated with Chronic Depot Medroxyprogesterone Acetate Use."[15] The abstract reported on 25 individuals who developed one or more intracranial meningiomas related to chronic use of Depo-Provera. Of the twenty-five (25) patients, ten (10) were instructed to cease Depo-Provera use, after which five (5) of those patients had "clear evidence of tumor shrinkage," leading the authors to conclude "there appears to be a clear progestin meningioma syndrome associated with chronic DMPA use."

85. In 2024, the French National Agency for Medicines and Health Products Safety

[14] Hage, et al., "Estrogen and progesterone therapy and meningiomas," *Endocrinology,* Vol. 163, pp. 1-10 (2022).
[15] Abou-Al-Shaar, et al., "Skull base meningiomas as part of a novel meningioma syndrome associated with chronic depot medroxyprogesterone acetate use," *J Neurol Surg Part B Skull Base,* Vol. 84:S1-344 (2023).

along with several French neurosurgeons, epidemiologist, clinicians, and researchers published a large case control study in the *British Medical Journal* (*BMJ*), one of the premier scientific journals in the world, to assess the risk of intracranial meningioma with the use of numerous progestogens among women in France, hereinafter referred to as the *Roland* study.[16]

86. By way of history, the *Roland* study noted that concerns over meningiomas associated with high dose progestogen medications resulted in the recent discontinuation of three such medications in France and the EU. Specifically, there were "postponements in the prescription of chlormadinone acetate, nomegestrol acetate, and cyproterone acetate, following the French and European recommendations to reduce the risk of meningioma attributable to these progestogens in 2018 and 2019."[17]

87. The study analyzed 18,061 cases of women undergoing surgery for intracranial meningioma between 2009 and 2018. The study found that "prolonged use of ... medroxyprogesterone acetate [Depo-Provera] ... was found to increase the risk of intracranial meningioma." Specifically, the authors found that prolonged use of Depo-Provera resulted in a 555% increased risk of developing intracranial meningioma. The study authors concluded "[t]he increased risk associated with the use of injectable medroxyprogesterone acetate, a widely used contraceptive," was an important finding. The authors also noted Depo-Provera is "often administered to vulnerable populations," i.e., lower-income women who have no other choice but to take the subsidized option which only requires action every three months to remain effective for its intended use of preventing pregnancy, and, in the case of the subcutaneous variant, treating

[16] Roland, et al., "Use of progestogens and the risk of intracranial meningioma: national case-control study," *BMJ*, Vol. 384, published online Mar. 27, 2024 at https://doi.org/10.1136/bmj-2023-078078 (last accessed December 30, 2024).
[17] *See id.*

endometriosis.

88. The 2024 *Roland* study published in *BMJ* studied the effect of several other progestogen-based medications. Three study subjects showed no excess risk of intracranial meningioma surgery with exposure to oral or intravaginal progesterone or percutaneous progesterone, dydrogesterone or spironolactone, while no conclusions could be drawn for two others due to lack of exposed cases. The other medications, including medroxyprogesterone acetate (Depo-Provera), were found to be associated with an increased risk of intracranial meningioma, with Depo-Provera having by far the second highest increased risk, surpassed only by the product cyproterone acetate, which had already been withdrawn from the market due to its association with meningioma.

89. Depo-Provera had by far the highest risk of meningioma surgeries amongst progesterone contraceptive products studied, rendering Depo-Provera more dangerous than other drugs and treatment options designed to prevent pregnancy due to the unreasonably increased risk of injury associated with intracranial meningioma, including but not limited to seizures, vision problems, and even death.

90. Further, the *Roland* study found the longer duration of exposure had a greater risk noting the results show that three quarters of the women in the case group who had been exposed for more than a year had been exposed for more than three years.

91. The *Roland* study noted that among cases of meningioma observed in the study, 28.8% (5,202 / 18,061) of the women used antiepileptic drugs three years after the index date of intracranial surgery.

D. Defendants' Failure to Test Depo-Provera

92. Defendants knew or should have known of the potential impact of the drug to cause

the development of intracranial meningioma but failed to adequately study these adverse effects.

93. Furthermore, despite the fact that studies have emerged over the course of decades providing evidence of the meningioma-related risks and dangers of progesterone and progestins and Depo-Provera specifically, Defendants have failed to adequately investigate the threat that Depo-Provera poses to patients' well-being or warn the medical community and patients of the risk of intracranial meningioma and sequelae related thereto.

E. Defendants' Continuing Failure to Disclose Depo-Provera's Health Risks

94. According to the Drugs@FDA website, the label for Depo-Provera has been updated on at least fourteen (14) occasions since 2003, with the most recent update coming in July 2024.[18] Despite the fact there are at least fourteen (15) iterations of the Depo-Provera label, Defendants' labels have not contained any warning or any information whatsoever on the increased propensity of Depo-Provera to cause severe and debilitating intracranial meningioma like that suffered by Plaintiff.

95. Despite the aforementioned article in the *BMJ* and all the preceding medical literature cited above demonstrating the biological plausibility of the association between progesterone and meningioma, evidence of Depo-Provera related cases of meningioma and the evidence of other high dose progesterones causing meningiomas, Defendants have still made no change to the U.S. Depo-Provera label related to intracranial meningioma. Furthermore, Defendants have failed to take any steps to otherwise warn the medical community and Depo-Provera users of these significant health risks, despite changing the label as recently as July 2024 to include warnings about pregnancy-related risks, and despite Defendant Pfizer stating to The

[18] *See* Drugs@FDA:FDA-Approved Drugs- Depo-Provera, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020246 (last visited December 30, 2024).

Guardian when the *BMJ* article was released in April 2024: "We are aware of this potential risk associated with long-term use of progestogens and, in collaboration with regulatory agencies, are in the process of updating product labels and patient information leaflets with appropriate wording."[19]

96. Defendant Pfizer *has* changed the label in the EU and the UK and potentially in other countries. Specifically, Defendants' Depo-Provera label in the EU now contains the following addition under the section titled "**Special warnings and precautions for use**": "Meningioma: Meningiomas have been reported following long term administration of progestogens, including medroxyprogesterone acetate. Depo-Provera should be discontinued if a meningioma is diagnosed. Caution is advised when recommending Depo-Provera to patients with a history of meningioma."[20]

97. Additionally, Defendants' Package Leaflet in the EU which provides information for the patient states that "before using Depo-Provera[,]... it is important to tell your doctor or healthcare professional if you have, or have ever had in the past ... a meningioma (a usually benign tumor that forms in the layers of tissue that cover your brain and spinal cord)."[21]

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[19] Ian Sample, *Hormone medication could increase risk of brain tumours, French study finds*, THE GUARDIAN (Mar. 27, 2024), available at https://www.theguardian.com/society/2024/mar/27/hormone-medication-brain-tumours-risk-progestogens-study) (last accessed December 30, 2024).

[20] *See also* PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC) MINUTES OF PRAC MEETING ON 2-5 SEPTEMBER 2024 (Oct. 21, 2024) (last visited November 12, 2024) ("Having considered the available evidence in EudraVigilance, the literature, and the cumulative review submitted by the MAHs, PRAC concluded that there is sufficient evidence to establish a causal association between medroxyprogesterone acetate (MPA) and meningioma. Therefore, the product information should be updated to add meningioma as a contraindication and a warning . . . .").

[21] *See also* PFIZER, DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION – MEDROXYPROGESTERONE ACETATE: RISK OF MENINGIOMA AND MEASURES TO MINIMIZE THIS RISK (Oct. 7, 2024), available at https://assets.publishing.service.gov.uk/media/672a36c1fbd69e1861921b9c/Medroxyprogesterone_acetate_-_Risk_of_meningioma_and_measures_to_minimise_this_risk_-_to_publish.pdf (last visited November 12, 2024).

98. Nothing was or is stopping Defendants from adding similar language to the label and package insert for Depo-Provera in the United States. Defendants could have at any time made "moderate changes" to the label.

99. Specifically, Defendants could have filed a "Changes Being Effected" ("CBE") supplement under 21 C.F.R. § 314.70(c) to update Depo-Provera's label without any prior FDA approval.

100. Examples of "moderate" label changes that can be made via a CBE supplement explicitly include changes "to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction." By definition, and by regulation, such changes to add a warning based on newly acquired information—such as that imparted by newly emerging literature like the litany of studies cited above—are considered a "moderate change." 21 C.F.R. § 314.70(c)(6)(iii).

101. Recently, the Third Circuit reaffirmed that plain text interpretation of the CBE supplement process in a precedential decision holding that the defendant in that case, Merck, could not rely on a preemption defense based on an allegedly irreconcilable conflict between federal (FDCA) and state (civil tort) law so long as the warning could have been effected via a CBE change. *See generally In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, Case No. 22-3412, D.I. 82 at 73 on the docket (J. Jordan) (3d Cir. Sept. 20, 2024) (noting "the availability of a label change via a CBE supplement is problematic for Merck, as will very often be the case for pharmaceutical companies raising an impossibility defense").

102. Defendants could have also instructed physicians to consider its own safer alternative design, a lower dose medroxyprogesterone acetate injected subcutaneously instead of the more invasive and painful intramuscular injection method. Studies going back at least ten years

have shown that the 150 mg dose of Depo-Provera—when administered subcutaneously, instead of intramuscularly—is absorbed by the body at a similarly slower rate as the lower dose 104 mg Depo-SubQ Provera 104 version.[22] Nevertheless, Defendants never produced a 150 mg subcutaneous version.

103. Knowing that the lower dose 104 mg Depo-SubQ Provera 104 was equally effective and was easier to administer since it involved a smaller needle being injected only below the skin and not all the way into the muscle, Defendants could have educated the gynecology community that it had a safer alternative product to Depo-Provera which was more well known to prescribers and patients.

104. In Europe and other counties outside of the United States, this 104 mg subcutaneous dose has a more accessible trade name, "Sayana Press," unlike the unwieldy proprietary developmental name of "Depo-SubQ Provera 104". Sayana Press sold in Europe may be self-administered by patients, obviating the need for quarterly visits to a medical practitioner.

105. When Depo-SubQ Provera 104, under NDA number 21-583, submitted by Defendant Pharmacia & Upjohn, a subsidiary of Defendant Pfizer, was approved by the FDA on February 17, 2004, more than two decades ago, those Defendants submitted a proposed trade name that the FDA did not approve, so instead, the proprietary name Depo-SubQ Provera 104 was deemed to be the brand name.

106. Inexplicably, and presumably for commercially beneficial or contractual reasons, Defendant Pfizer made a conscious decision to not seek an alternative commercially more accessible brand name, and to not endeavor to more vigorously advocate for the sale of Depo-SubQ

[22] *See* Shelton, et al., "Subcutaneous DPMA: a better low dose approach," *Contraception*, Vol. 89, pp. 341-43 (2014).

Provera 104 to patients seeking contraception, despite knowing it had a lower safer and effective dosage which would mitigate the potential for adverse reactions engendered by a high dose progestin, including the risk of developing or worsening meningioma tumors.

107. The "lowest effective dose" is a well-known concept in the field of pharmaceutics wherein a drug-maker should seek to find the lowest possible dose at which the drug of interest is efficacious for the intended use, as any additional dosage on top of that lowest effective dose is inherently superfluous and can increase the risk of unwanted side effects.

108. Either change—adding a warning about the risk of meningioma based on "newly acquired information" or advising physicians to consider a switch to subcutaneous Depo-SubQ Provera 104—either on its own or taken together, would have constituted a "moderate change" or changes justifying a simple CBE supplement that Defendants could have effectuated immediately, and then simply notified the FDA thereafter. Yet, Defendants have failed to do so, and that failure continues to date.

109. Defendants ignored reports from patients and health care providers throughout the United States which indicated that Depo-Provera failed to perform as intended. Defendants also knew or should have known of the effects associated with long term use of Depo-Provera, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather than conducting adequate testing to determine the cause of these injuries for which it had notice or rule out Depo-Provera's design as the cause of the injuries, Defendants continued to falsely and misleadingly market Depo-Provera as a safe and effective prescription drug for contraception and other indications.

110. Defendants' Depo-Provera was at all times and is utilized and prescribed in a manner foreseeable to Defendants, as Defendants generated the instructions for use for Plaintiff

to receive Depo-Provera injections.

F. Regulatory Requirements for Brand and Generic Manufacturers

111. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C.S. §§ 301-393, is the regulatory scheme governing the approval and regulation of prescription drugs.

112. The FDA is the governing body and has the ultimate authority to determine whether a new prescription drug will be approved after finding it to be safe and effective for use.

113. Relevant here, brand-name manufacturers and generic manufacturers have different federal drug-labeling responsibilities.

114. A brand-name manufacturer seeking approval for a new product / drug is responsible for the accuracy and adequacy of its label. *See* 21 U.S.C.S. §§ 355(b)(1), (d).

115. A manufacturer seeking approval for a generic drug is responsible for ensuring that its label is the same as the brand-name drug. *See* 21 U.S.C.S. § 355(j)(2)(A)(v); §§ 355(j)(4)(G).

116. Through the "Changes Being Effected" ("CBE") rule, a brand-name manufacturer, upon discovering a clinically significant hazard, may modify its label to add or strengthen a contraindication, warning, precaution, or adverse reaction without first obtaining FDA approval for said change. 21 C.F.R. § 314.70(c)(6)(iii)(A).

117. Generic manufacturers, however, may not utilize the CBE process. A generic manufacturer may change a label only when necessary to match an updated brand-name label or to follow FDA instructions.

118. Ultimately, however, the FDA will review any CBE modification to a label. 21 C.F.R. § 314.70(c)(7). If the FDA rejects the change, it may order the manufacturer to cease distribution of the drug with the revised label. *See* 21 C.F.R. § 314.70(c)(7). R. §§ 314.94(a)(8), 314.127(a)(7).

119. Under the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Amendments, generic drug formulations can obtain FDA approval of a generic drug by showing bioequivalence to a reference-listed drug that has already been approved by the FDA. *See* 21 U.S.C.S. § 355(j)(2)(A).

120. A manufacturer seeking approval for a generic drug must also show that the labeling proposed for the generic drug is the same as the labeling approved for the brand-name drug. *See* 21 U.S.C.S. § 355(j)(2)(A)(v).

121. Thus, generic manufacturers have an ongoing federal duty of sameness regarding their warning labels.

122. Based on the United States Supreme Court's decisions in *PLIVA v. Mensing* and *Mutual Pharmaceutical Co. v. Bartlett*, only brand-name manufacturers have the ability to initiate label changes, and generic manufacturers cannot be liable in tort under state law for failure to warn because they are required to mirror the brand-name manufacturer's labels.

123. Accordingly, a brand-name manufacturer owes a duty to use reasonable care in its warnings because anyone who takes or prescribes the drug must rely on the warnings of the brand name drug.

124. Further, it is reasonably foreseeable that a physician will rely upon a brand name manufacturer's representations, or the absence thereof, about the risk of side effects of its drug when deciding to prescribe the drug for a patient, regardless of whether the pharmacist fills the prescription with the brand-name drug or a generic form of the drug.

125. Plaintiff and Plaintiff's physicians foreseeably used Depo-Provera and did not misuse or alter Depo-Provera in an unforeseeable manner.

126. Through its affirmative misrepresentations and omissions, Defendants actively

concealed from Plaintiff and her physicians the true and significant risks associated with Depo-Provera use.

127. As a result of Defendants' actions, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' conduct.

128. As a direct result of being prescribed and consuming Depo-Provera, Plaintiff has been permanently and severely injured, having suffered serious consequences.

129. As a direct and proximate result of her Depo-Provera use, Plaintiff suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress, along with economic loss including past and future medical expenses.

130. Despite diligent investigation by Plaintiff into the cause of these injuries, including consultations with medical providers, the nature of Plaintiff's injuries and damages and their relationship to Depo-Provera was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

131. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold information from Plaintiff, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of, and exposure to, Depo-Provera, particularly over extended periods of time.

132. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold safety-related warnings from the Plaintiff, and the general public concerning the

known hazards associated with the use of, and exposure to, Depo-Provera, particularly over extended periods of time.

133. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to withhold instructions from the Plaintiff, her family members, and the general public concerning how to identify, mitigate, and/or treat known hazards associated with the use of, and exposure to, Depo-Provera, particularly over extended periods of time.

134. The aforementioned studies reveal that discontinuing use of high dose progesterone and progestin, including Depo-Provera, can retard the growth of meningiomas but failed to warn the medical community and the Plaintiff of this method to mitigate the damage of a developing meningioma.

135. Defendants willfully, wantonly, and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately not study the long-term safety and efficacy of Depo-Provera, particularly in chronic long-term users of Depo-Provera.

136. Defendants failed to disclose a known defect and, instead, affirmatively misrepresented that Depo-Provera was safe for its intended use. Defendants disseminated labeling, marketing, promotion and/or sales information to Plaintiff, her healthcare providers, and the general public regarding the safety of Depo-Provera knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with long-term Depo-Provera use. Defendants did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Depo-Provera's safety.

137. Further, Defendants actively concealed the true risks associated with the use of Depo-Provera, particularly as they relate to the risk of serious intracranial meningioma, by affirmatively representing in numerous communications, which were disseminated to Plaintiff, her

healthcare providers, and which included, without limitation, the Package Insert and the Medication Guide, that there were no warnings required to safely prescribe and take Depo-Provera and no intracranial meningioma-related adverse side effects associated with use of Depo-Provera.

138. Due to the absence of any warning by the Defendants as to the significant health and safety risks posed by Depo-Provera, Plaintiff was unaware that Depo-Provera could cause the development of a serious and debilitating intracranial meningioma, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

139. Due to the absence of any instructions for how to identify and/or monitor Depo-Provera patients for potential intracranial meningioma-related complications, Plaintiff was unaware that Depo-Provera could cause serious, intracranial meningioma-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

140. Given Defendants' conduct and deliberate actions designed to deceive Plaintiff, Plaintiff's healthcare providers, and the general public, with respect to the safety and efficacy of Depo-Provera, Defendants are estopped from relying on any statute of limitations defenses.

141. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to Depo-Provera were not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

142. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injuries and the connection between the injuries and Defendants' tortious conduct.

COUNT I
NEGLIGENCE
(Against All Defendants)

143. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

144. A brand-name manufacturer, like Defendant Pfizer, that controls the contents of the label on a generic drug owes a duty to consumers of that generic drug not to act in reckless disregard of an unreasonable risk of death or grave bodily injury. Defendants did, in fact, act with reckless disregard by failing to update the label for Depo-Provera to warn about the risk of meningioma with its use.

145. At all times relevant herein, it was the duty of Defendants to use reasonable care in the design, labeling, manufacturing, testing, marketing, distribution and/or sale of Depo-Provera.

146. Defendants failed to exercise ordinary care in the labeling, design, manufacturing, testing, marketing, distribution, and/or sale of Depo-Provera in that Defendants knew or should have known that Depo-Provera created a high and foreseeable risk of unreasonable harm to Plaintiff and other users. In fact, Defendants acted with reckless disregard in labeling, designing, manufacturing, testing, marketing, distributing, and selling Depo-Provera.

147. Defendants breached its duty of care to the Plaintiff and her physicians, in the testing, monitoring, and pharmacovigilance of Depo-Provera.

148. In complete reckless disregard of its duty, Defendants committed one or more of

the following reckless acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Depo-Provera without thorough and adequate pre- and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Depo-Provera while recklessly and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Depo-Provera;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Depo-Provera was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Depo-Provera was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers of the known and knowable product's risk of harm which was unreasonable and that there were safer and effective alternative products available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Depo-Provera;

g. Advertising, marketing, and recommending the use of Depo-Provera, while concealing and failing to disclose or warn of the dangers known and knowable by Defendants to be connected with, and inherent in, the use of Depo-Provera;

h. Representing that Depo-Provera was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing to manufacture and sell Depo-Provera with the knowledge that Depo-Provera was unreasonably unsafe and dangerous;

j. Failing to use reasonable and prudent care in the design, research,

testing, manufacture, and development of Depo-Provera so as to avoid the risk of serious harm associated with the use of Depo-Provera;

k. Failing to design and manufacture Depo-Provera so as to ensure the drug was at least as safe and effective as other similar products;

l. Failing to ensure the product was accompanied by proper and accurate warnings about monitoring for potential symptoms related to intracranial meningioma associated with the use of Depo-Provera;

m. Failing to ensure the product was accompanied by proper and accurate warnings about known and knowable adverse side effects associated with the use of Depo-Provera and that use of Depo-Provera created a high risk of severe injuries;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Depo-Provera; and

o. Failing to sell a product with the lowest effective dose knowing that there were safer lower effective dose formulations.

149. A reasonable manufacturer, designer, distributor, promoter, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

150. As a direct and proximate result of the Defendants' reckless and negligent testing, monitoring, and pharmacovigilance of Depo-Provera, Defendants introduced a product that they knew or should have known would cause serious and permanent injuries related to the development of intracranial meningioma, and Plaintiff has been injured tragically and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

151. Here, Pfizer—the brand-name drug manufacturer—provides an inadequate warning for its own product (Depo-Provera), and it knows or should know that it puts at risk not only the users of its own product, but also the users of the generic Depo-Provera.

152. As a direct and proximate result of one or more of the above-stated reckless acts by Defendants, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

COUNT II
PRODUCTS LIABILITY – FAILURE TO WARN
(Against All Defendants)

153. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

154. Under South Carolina law, a product is defective if a product fails to contain adequate warnings, the inadequate warnings render the product unreasonably dangerous to the user or consumer, and the inadequate warning proximately cause the damages for which recovery is sought. A drug manufacturer has a duty to adequately warn the prescribing physician of any known adverse effects which might result from the use of its prescription drug.

155. Defendants failed to properly and adequately warn and instruct Plaintiff and her health care providers as to the foreseeable dangers and risks associated with use of Depo-Provera. Defendants failed to properly package or label their products to give reasonable warnings of danger about Depo-Provera to Plaintiff and her health care providers.

156. Defendants were reckless in their failure to warn Ms. Odom and her doctor(s) regarding adverse reactions that were known at the time Ms. Odom was prescribed and injected with their Depo-Provera products.

157. Defendants had a duty to warn Plaintiff, Plaintiff's physicians, and consumers of Depo-Provera of the known and/or knowable dangers and serious side effects, including serious

and potentially debilitating intracranial meningioma, as it was reasonably foreseeable to Defendants that Depo-Provera could cause such injuries.

158. Defendants, as manufacturers, distributers, and marketers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known based on information that was available and generally accepted in the scientific community that warnings and other clinically relevant information and data which they distributed regarding the risks associated with the use of Depo-Provera were inadequate.

159. As the only manufacturer with the ability under FDA regulations to initiate labeling changes and/or report to the FDA findings, such as those that led to the foreign label changes, Defendants Pfizer, Pharmacia & Upjohn, and Pharmacia had a duty to all users of drugs marketed under the FDA-approved label, including users of generic equivalents.

160. Brand-name manufacturers, like Defendants Pfizer, Pharmacia & Upjohn, and Pharmacia, that control the contents of the label on a generic drug owes a duty to consumers of that generic drug not to act in reckless disregard of an unreasonable risk of death or grave bodily injury. Defendants did, in fact, act with reckless disregard by failing to update the label for Depo-Provera and its generic equivalents to warn about the risk of meningioma with its use.

161. Defendants Viatris, Greenstone, and Prasco did not provide an adequate warning regarding the side effects of Depo-Provera at the time Plaintiff was prescribed and injected with the brand-name and generic medication.

162. Defendants acted or intentionally failed to act—in breach of their duty to Plaintiff regarding warning of the risks associated with Depo-Provera—knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than

that which is necessary to make his conduct negligent.

163. Plaintiff and Plaintiff's treating physicians did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information or data was communicated to Plaintiff or to Plaintiff's treating physicians.

164. Defendants had and continue to have a duty to provide adequate warnings and instructions for Depo-Provera, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately understand, test, and monitor their product.

165. Defendants had and continue to have a duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data generally accepted within the scientific community regarding the risks and dangers associated with Depo-Provera, as it became or could have become available to Defendants.

166. At all times material herein, Defendants acted with reckless disregard and knew, or in the exercise of reasonable care should have known, that Depo-Provera had inadequate instructions and/or warnings.

167. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to:

a. Failing to accompany their product with proper and adequate warnings, labeling, or instructions concerning the potentially dangerous, defective, unsafe, and deleterious propensity of Depo-Provera and of the risks associated with its use, including the severity and potentially irreversible nature of such adverse effects;

b. Disseminating information to Plaintiff and Plaintiff 's physicians that was recklessly and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

c. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and

health risks;

d. Failing to adequately test and/or warn about the use of Depo-Provera, including, without limitations, the possible adverse side effects and health risks caused by the use of Depo-Provera;

e. Failure to adequately warn of the risks that Depo-Provera could cause the development of intracranial meningioma and sequelae related thereto;

f. Failure to adequately warn of the risk of serious and potentially irreversible injuries related to the development of intracranial meningioma, a brain tumor;

g. Failure to instruct patients, prescribers, and consumers of the need for al monitoring when taking Depo-Provera for symptoms potentially related to the development of intracranial meningioma;

h. Failure to instruct patients, prescribers, and consumers of the need to discontinue Depo-Provera in the event of symptoms potentially related to the development of intracranial meningioma;

i. Failing to provide instructions on ways to safely use Depo-Provera to avoid injury, if any;

j. Failing to explain the mechanism, mode, and types of adverse events associated with Depo-Provera;

k. Failing to provide adequate training or information to medical care providers for appropriate use of Depo-Provera and patients taking Depo-Provera;

l. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use;

m. Failing to warn that there is a safer feasible alternative with a lower effective dose of progestin; and

n. Failing to warn that the 150 mg dosage of progestin injected intramuscularly was an excessive and thus toxic dose capable of causing and or substantially contributing to the development and growth of meningioma tumors.

168. Defendants knew or should have known of the risk and danger of serious bodily harm from the use of Depo-Provera but failed to provide an adequate warning to patients and

prescribing physicians for the product, including Plaintiff and Plaintiff's prescribing physicians, despite knowing the product could cause serious injury.

169. Plaintiff was prescribed and used Depo-Provera for its intended purpose.

170. Plaintiff could not have known about the dangers and hazards presented by Depo-Provera.

171. The warnings given by Defendants were not accurate, clear, or complete, and/or were ambiguous.

172. The warnings, or lack thereof, that were given by Defendants failed to properly warn prescribing physicians, including Plaintiff's prescribing physician, of the known and knowable risk of serious and potentially irreversible injuries related to the development of intracranial meningioma, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries and to discontinue use when symptoms of meningioma manifest.

173. The warnings that were given by the Defendants failed to properly warn Plaintiff and prescribing physicians of the prevalence of intracranial meningioma and sequelae related thereto.

174. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff and prescribing physicians of the dangers associated with Depo-Provera. Had Plaintiff received adequate warnings regarding the risks of Depo-Provera, Plaintiff would not have used the product.

175. Defendants' reckless disregard for the information disseminated regarding the dosing information, marketing, testing, and warnings of Depo-Provera was a proximate cause of Plaintiff's injuries and damages.

176. The risk of meningioma was reasonably foreseeable at the time of sale and could have been discovered by way of reasonable testing prior to marketing the product. Defendants recklessly failed to conduct such reasonable testing.

177. Defendants intentionally failed to inform the public, including Plaintiff and her implanting surgeon, of the risk of meningioma with use of Depo-Provera.

178. Instead, Defendants chose to over-promote the safety, efficacy, and benefits of the Products.

179. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Depo-Provera, she would not have purchased, used, consented to, or relied on the information given regarding Depo-Provera.

180. As a direct and proximate result of Defendants' reckless failure to warn, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT III

PRODUCTS LIABILITY – DESIGN DEFECT (S.C. Code § 15-73-10) (Against Defendants Pfizer, Pharmacia & Upjohn, and Pharmacia)

181. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

182. Under South Carolina law, to demonstrate a product is defectively designed, a seller is liable for physical harm caused to the consumer if the seller sold a product in a defective condition unreasonable dangerous to the consumer, the seller is engaged in the business of selling such a product, and the product is expected to and does reach the consumer without substantial

change in the condition in which it is sold.

183. Plaintiff, ordinary consumers, and prescribers would not expect a contraceptive drug designed, marketed, and labeled for contraception to cause intracranial meningioma.

184. The dozens of Depo-Provera injections supplied to Plaintiff by Defendants were defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, provided an excessive dose of progestin for its purpose and posed a risk of serious and potentially debilitating intracranial meningioma to Plaintiff and other consumers.

185. The Depo-Provera supplied to Plaintiff by Defendants was defective in design or formulation in that its effectiveness as a contraceptive did not outweigh the risks of serious and potentially debilitating intracranial meningioma posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of the Depo-Provera drug makes the product unreasonably dangerous.

186. Depo-Provera's design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable manner. It was more dangerous than Plaintiff expected.

187. Feasible and suitable alternative designs have existed at all times relevant as compared to Defendants' 150mg Depo-Provera.

188. Depo-SubQ Provera 104 is a lower dosage version of Depo-Provera that contains 104 mg / 0.65mL and is injected subcutaneously every three (3) months. According to the label, Depo-SubQ Provera 104 can be used for both contraception and treatment of endometriosis.

189. Depo-SubQ Provera 104 never attained meaningful market share, and Defendant failed to promote the product to the medical community as a safer and equally effective method of

contraception for women choosing to receive quarterly injections.

190. Defendants failed to promote and encourage conversion of the prescribing gynecological community to Depo-SubQ Provera 104, fearing that doing so could instill a concern of safety as to the risks of its high dose progesterone long standing product, Depo-Provera.

191. The intended or actual utility of Depo-Provera is not of such benefits to justify the risk of intracranial meningioma which may cause severe and permanent injuries, thereby rendering the product unreasonably dangerous.

192. The design defects render Depo-Provera more dangerous than other drugs and therapies designed for contraception and causes an unreasonable increased risk of injury, including, but not limited, to potentially debilitating intracranial meningioma and sequelae related thereto. This unreasonable risk existed at the time the product used by Plaintiff left the control of Defendants.

193. Defendants knew or should have known through testing, generally accepted scientific knowledge, advances in the field, published research in major peer-reviewed journals, or other means, that Depo-Provera created a risk of serious and potentially debilitating intracranial meningioma and sequelae related thereto.

194. Defendants' actions, when viewed objectively from Defendants' standpoint at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants had an actual, subjective awareness of the risk involved but nevertheless intentionally and recklessly proceeded with conscious indifference to the rights, safety, or welfare of others.

195. Defendants acted or intentionally failed to act—in breach of their duty to Plaintiff regarding designing Depo-Provera in a way that does not render it unreasonably dangerous—

knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than that which is necessary to make his conduct negligent.

196. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to recklessly and carelessly:

a. Failing to use due care in developing, testing, designing, and manufacturing Depo-Provera so as to avoid the aforementioned risks to individuals when Depo-Provera was being used for contraception and other indications;

b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Depo-Provera;

c. Designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendants knew or should have known could cause injury to Plaintiff; and

d. Failing to use due care in developing, testing, designing, and manufacturing Depo-Provera with the lowest effective dose as a safer alternative which clearly existed at all relevant times so as to avoid the aforementioned risks to individuals when high dose progestin Depo-Provera was being used for contraception.

197. Defendants' recklessness and Depo-Provera's failures arise under circumstances precluding any other reasonable inference other than a defect in Depo-Provera.

198. At all times material herein, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, testing, and research to assure the safety of Depo-Provera when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and

Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Depo-Provera.

199. At all times material herein, Defendants failed to exercise reasonable care and the duty of an expert and knew, or in the exercise of reasonable care should have known, that Depo-Provera was not properly manufactured, designed, compounded, tested, inspected, packaged, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, or a combination of these acts.

200. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Depo-Provera caused the product to fail to function as expected and thus was a proximate cause of Plaintiff's injuries and damages.

201. At all relevant times herein, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Depo-Provera, and placed it into the stream of commerce in a defective and unreasonably dangerous condition.

202. The Depo-Provera injections received by Plaintiff were expected to and did reach Plaintiff without substantial change in the condition in which the product was sold.

203. Defendants' reckless disregard for the design of Depo-Provera was a proximate cause of Plaintiff's injuries and damages.

204. The risk of meningioma was reasonably foreseeable at the time of sale and could have been discovered by way of reasonable testing prior to marketing the product. Defendants recklessly failed to conduct such reasonable testing.

205. As a direct and proximate result of Defendants' negligence, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for

the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT VI
MISREPRESENTATION
(Against All Defendants)

206. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

207. At all relevant times, Defendants negligently provided Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failed to disclose material facts concerning Depo-Provera, including, but not limited to, misrepresentations regarding the safety and known risks of Depo-Provera.

208. The information distributed by the Defendants to the public, the medical community, Plaintiff, and her physicians, including advertising campaigns, labeling materials, print advertisements, commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of Depo-Provera.

209. For example, as stated above, the United States label for Depo-Provera does not contain a warning for the risk of meningioma, while the Canadian label for Depo-Provera does include such a warning.

210. Defendants' intent and purpose in making these misrepresentations or omissions was to deceive and defraud the public and the medical community, including Plaintiff and her physicians; to falsely assure them of the quality of Depo-Provera and induce the public and medical community, including Plaintiff and her physicians to request, recommend, purchase, and prescribe Depo-Provera.

211. Defendants had a pecuniary interest in making the false statements regarding the safety of Depo-Provera.

212. The Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical device manufacturers, Plaintiff, her physicians, and the public, the known risks of Depo-Provera, including its propensity to cause intracranial meningioma and sequelae related thereto. The representations made by Defendants, in fact, were false.

213. Defendants made continued omissions in the Depo-Provera labeling, including promoting it as safe and effective while failing to warn of its propensity to cause intracranial meningioma and sequelae related thereto.

214. Defendants made additional misrepresentations beyond the product labeling by representing Depo-Provera as safe and effective for contraception and other indications with only minimal risks.

215. Defendants misrepresented and overstated the benefits of Depo-Provera to Plaintiff, Plaintiff's physicians, and the medical community without properly advising of the known risks associated with intracranial meningioma and sequelae related thereto.

216. Defendants misrepresented and overstated that the Depo-Provera dosage was needed to protect against pregnancy when Defendants knew that a safer alternative existed with forty-six (46) fewer mg per dose of the powerful progestin being ingested quarterly in women, and when Defendants could have warned and recommended usage of Depo-SubQ Provera 104 instead.

217. In doing so, Defendants failed to exercise that degree of diligence and expertise the public is entitled to expect of it. Defendants failed to exercise ordinary care in the representations concerning Depo-Provera while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants

negligently misrepresented the Products' high risk of unreasonable, dangerous, and adverse side effects, including the risk of meningiomas.

218. In reasonable and justifiable reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's physicians were induced to, and did use Depo-Provera, thereby causing Plaintiff to endure severe and permanent injuries.

219. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's physicians were unable to associate the injuries sustained by Plaintiff with her Depo-Provera use, and therefore unable to provide adequate treatment. Defendants knew or should have known that the Plaintiff, Plaintiff's physicians, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

220. Plaintiff and her physicians would not have used or prescribed Depo-Provera had the true facts not been concealed and/or had been disclosed by the Defendants.

221. Defendants had sole access to many of the material facts concerning the defective nature of Depo-Provera and its propensity to cause serious and dangerous side effects.

222. At the time Plaintiff was prescribed and administered Depo-Provera, Plaintiff and her physicians were unaware of Defendants' negligent misrepresentations and omissions.

223. Defendants owed a duty to Plaintiff not to knowingly act in reckless disregard of an unreasonable risk of death or grave bodily injury.

224. Plaintiff and her physicians reasonably relied upon the misrepresentations and omissions made by the Defendants, where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of Depo-Provera.

225. Plaintiff and her physicians' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

226. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT VII
BREACH OF EXPRESS WARRANTY (S.C. Code § 36-2-313)
(Against All Defendants)

227. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

228. At all relevant times herein, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Depo-Provera, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

229. Plaintiff and/or her prescribing physicians were at all relevant times in privity with Defendants.

230. Defendants expressly warranted to Plaintiff, Plaintiff's physicians, and the general public, by and through Defendants and/or their authorized agents or sales representatives, in publications, labeling, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that Depo-Provera was safe, effective, fit and proper for its

intended use.

231. Depo-Provera materially failed to conform to those representations made by Defendants, in package inserts and otherwise, concerning the properties and effects of Depo-Provera, which Plaintiff purchased and consumed via intramuscular injection in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Depo-Provera as sold to Plaintiff.

232. Defendants expressly warranted that Depo-Provera was safe and well-tolerated. However, Defendants did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Depo-Provera was dangerous to the well-being of Plaintiff and others.

233. Depo-Provera does not conform to those express representations because it is defective, is not safe, and has serious adverse side effects.

234. Defendants' Depo-Provera was expected to reach and did in fact reach consumers, including Plaintiff and her prescribing physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

235. Defendants breached various express warranties with respect to Depo-Provera including the following particulars:

a) Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Depo-Provera was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with being injected with Depo-Provera;

b) Defendants intentionally omitted information regarding feasible and suitable alternative designs to Defendants' 150mg Depo-Provera.

Depo-SubQ Provera 104 is a lower dosage version of Depo-Provera that contains 104 mg / 0.65mL and is injected subcutaneously every three (3) months;

c) Defendants represented to Plaintiff and her physicians and healthcare providers that Depo-Provera was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that Depo-Provera was not safer than alternatives available on the market; and

d) Defendants represented to Plaintiff and her physicians and healthcare providers that Depo-Provera was more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of Depo-Provera.

236. Such representations, affirmations of fact, and omissions as those listed became the basis of the bargain. Plaintiff's physicians justifiably relied on Defendants' representations through Defendants' marketing and sales representatives in deciding to prescribe Depo-Provera over other alternative treatments on the market, like Depo-SubQ Provera 104, and Plaintiff justifiably relied on Defendants' representations in deciding to purchase and use the drug.

237. Plaintiff purchased and ingested Depo-Provera without knowing that the drug is not safe and well-tolerated, but that Depo-Provera instead causes significant and irreparable damage through the development of debilitating intracranial meningioma.

238. As a direct and proximate result of Defendants' breaches of warranty, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, past and future medical care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT IX
BREACH OF IMPLIED WARRANTY (S.C. Code §§ 36-2-314(2); 36-2-315)
(Against All Defendants)

239. Plaintiff incorporates by reference each and every preceding paragraph as though

fully set forth herein.

240. At all relevant times herein, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Depo-Provera, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants. Defendants were at all relevant times merchants with respect to good like the product used by Plaintiff.

241. The risk of meningioma was reasonably foreseeable at the time of sale and could have been discovered by way of reasonable testing prior to marketing the product. Defendants failed to conduct such reasonable testing.

242. Defendants knew or in the exercise of reasonable care should have known the ordinary and particular uses and purposes for which the Products were intended, including use by women such as Plaintiff for contraceptive purposes, and impliedly warranted that the products were of merchantable quality and safe for such uses.

243. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

244. Defendants were the sellers of the Depo-Provera and sold Depo-Provera to be taken for contraception or to treat endometriosis, among other indications. Plaintiff was prescribed and purchased Depo-Provera for these intended purposes.

245. When the Depo-Provera was prescribed by Plaintiff's physicians and taken by Plaintiff, the product was being prescribed and used for the ordinary purpose for which it was intended.

246. Defendants impliedly warranted their Depo-Provera product, which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of

merchantable quality, fit, and safe for the common, ordinary, and intended uses for which the product was sold.

247. Defendants' Depo-Provera was expected to reach and did in fact reach consumers, including Plaintiff and her prescribing physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

248. Defendants breached various express warranties with respect to Depo-Provera including the following particulars:

a) Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Depo-Provera was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with being injected with Depo-Provera;

b) Defendants represented to Plaintiff and her physicians and healthcare providers that Depo-Provera was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that Depo-Provera was not safer than alternatives available on the market; and

c) Defendants represented to Plaintiff and her physicians and healthcare providers that Depo-Provera was more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of Depo-Provera.

249. Defendants breached their implied warranties of the Depo-Provera product because the Depo-Provera sold to Plaintiff was not fit for its ordinary purpose as a contraceptive or to treat endometriosis safely and effectively, among other uses.

250. When the Products were distributed into the stream of commerce and sold by Defendants, they were unsafe for their intended use, and not of merchantable quality, as warranted by Defendants as use of the Products by women for contraception creates a dangerous and

unreasonably high risk of meningiomas.

251. Defendants could have also instructed physicians to consider its own safer alternative design, a lower dose medroxyprogesterone acetate injected subcutaneously instead of the more invasive and painful intramuscular injection method. This alternative design was available and feasible but was not employed by Defendants in this case.

252. The Depo-Provera would not pass without objection in the trade; is not of fair average quality; is not fit for its ordinary purposes for which the product is used; was not adequately contained, packaged and labeled; and fails to conform to the promises or affirmations of fact made on the container or label.

253. The Products did not conform to these implied warranties violation of South Carolina Ann. Code §§ 36-2-314(2); 36-2-315, and South Carolina common law, as the Products were defective in design and manufacture and design and were therefore not fit for their intended uses and were not designed, manufactured, or sold in accordance with good design, manufacturing, or industry standards. The Products were not fit for the common, ordinary and intended uses, including usage by for contraception. Therefore, Defendants have breached the implied warranty of merchantability as well as the implied warranty of fitness for a particular purpose. Such breaches by Defendants were a proximate cause of the injuries and damages sustained by Plaintiff.

254. Defendants' breach of their implied warranties resulted in the intramuscular administration of the unreasonably dangerous and defective product into Plaintiff, which placed Plaintiff's health and safety at risk and resulted in the damages alleged herein.

255. As a direct and proximate result of reliance upon Defendants' breaches of warranty, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss

of capacity for the enjoyment of life, past and future medical care and treatment, loss of earnings, loss of consortium, loss of ability to earn money and other economic losses, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

1. Award Plaintiff compensatory damages in an amount to be determined at trial, and also including, but not limited to:

   a. General Damages for severe physical pain, mental suffering, inconvenience, and loss of the enjoyment of life;

   b. Special Damages, including all expenses, incidental past and future expenses, medical expenses, and loss of earnings and earning capacity;

2. Award interest as permitted by law;

3. Award reasonable attorneys' fees and costs, as provided for by law; and

4. Grant such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all Counts and as to all issues.

Dated: March 6, 2025

Respectfully Submitted,

/s/ *Kristen Hermiz*

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